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PATENT
Docket No. 377882001500

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Tamara Venegas

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Stephen TUCK and Gary VAN NEST

Serial No.: 09/713,136

Filing Date: November 14, 2000

For: IMMUNOMODULATORY COMPOSITIONS CONTAINING AN IMMUNOSTIMULATORY SEQUENCE LINKED TO ANTIGEN AND METHODS OF USE THEREOF

Examiner: P. Huynh

Group Art Unit: 1644

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is in response to the Office Action dated May 17, 2001, which sets forth a restriction requirement for pending claims 1-42. A petition and fee for a two-month extension of time are attached, making this response due on or before August 17, 2001. Accordingly, this response is timely filed.

ELECTION OF INVENTION

Claims 1-42 are pending in this application. Restriction has been required among the following allegedly distinct groups of inventions:

Group I (claims 1-10): drawn to a composition;

Group II (claims 11-24 and 37-42): drawn to a method of modulating an immune response wherein the modulation is inhibitory;

Group III (claims 11-24 and 31-36): drawn to a method of modulating an immune response wherein the modulation is stimulatory;

Group IV (claims 25-30): drawn to a method of treating an allergic condition.

Applicants hereby elect Group I (claims 1-10) with traverse. Applicants expressly reserve their right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

Applicants traverse the restriction among Groups II, III and IV on the grounds that the Examiner has not provided adequate basis for the restriction of claims into these groups according to M.P.E.P. §806.05. These groups can be and should be properly examined together (and, as discussed below, should be rejoined as method claims with regard to Group I which incorporate all limitations of any allowable composition claims).

Improper division of generic claims reciting "immune modulation" into separate groups based on alleged mutually exclusive inhibitory and stimulatory aspects of immune modulation

In point 4 of the Office Action, the Examiner states that modulation of the immune function includes stimulatory or inhibitory changes, which are allegedly "mutually exclusive", and is a basis for splitting the generic claims which recite methods of modulating an immune response into separate groups (and thus separate patent applications), Groups II and III. The Examiner provides no support for this conclusory statement regarding the alleged mutually exclusive nature of the stimulation or inhibition of an immune response. Applicants respectfully point out that, contrary to the Examiner's statement, in the context of the immune system, modulation of an immune response can involve stimulation of certain aspects and inhibition of

other aspects of immune function. Thus, these aspects are not necessarily mutually exclusive.[1] For example, the specification describes methods of suppressing one or more aspects of an immune response as well as stimulating one or more aspects of an immune response through administering a composition of the invention. See, for example, page 8, lines 19-26; page 67, line 22, to page 68, line 8; page 70, lines 1-17; Examples 2-4.

Applicants respectfully point out that 35 U.S.C. §121 specifies that division of application for invention is proper "[i]f two or more independent and distinct inventions are claimed in one application." The courts have stated that a restriction requirement under this section cannot be applied to one claim; in other words, a single claim cannot be subdivided into separate, restricted groups. *See* In re Harnish, 631 F.2d 716, 721 (CCPA 1980) (stating that "court held that §121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality of narrower claims before examination on the merits would be made"). "If...a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification." In re Weber, 580 F.2d 455, 458 (CCPA 1978). Applicants respectfully request that the Examiner provide the legal basis for bifurcating a single claim in this instance. If anything, the splitting of "modulation" as the Examiner has (with which Applicants disagree), is a question of genus-species, not an invention subject to restriction.

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[1] Applicants also note that the general test to determine if the species are mutually exclusive is "the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while the second claim recites limitations disclosed only for the second species and not the first." MPEP § 806.04(f). As this section states, such a restriction is based on mutually exclusive species between first and second claims. It does not discuss a restriction based on a single claim.

Incorrect basis for division into Groups II, III and IV

The division of the claims among Groups II, III and IV is also allegedly supported with the statement that "[g]roups II-IV are methods of treating different diseases that differ with respect to etiology and require different ingredients and process steps to accomplish different endpoints since stimulation and inhibition are mutually exclusive." Office Action, page 3, point 5. Applicants respectfully disagree with this statement. First, the claims of groups II and III do not recite treating a disease, as stated by the Examiner. Second, the claims in groups II-IV do not require "different ingredients and process steps" to accomplish different endpoints, and the Examiner has provided no example of different ingredients or process steps or any basis for this alleged "requirement." In fact, the claims recite the same steps, *e.g.*, administering the claimed compositions. Third, as division of the claims among Groups II-IV is based on the incorrect assertion that immune stimulation and inhibition are mutually exclusive (". . .require different ingredients and process steps to accomplish different endpoints since stimulation and inhibition are mutually exclusive", Office Action at page 3, emphasis added), the proposed restriction should not stand.

The Examiner also states that the inventions "have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter. . ." Office Action, page 3, point 6. However, Groups II-IV all are deemed to be in the same class (424) and subclass (184.1). Thus, this provides no basis for the statement that these groups have "acquired a separate status in the art". Moreover, the Examiner has provided no basis for the assertion that these groups represent "recognized divergent subject matter." (Emphasis added.)

The Examiner has also provided no basis for any undue search burden with respect to these claims. M.P.E.P. §803. Based on their identical classification and subclassification status, it is hard to imagine any undue search burden would arise. Applicants also question why the composition claims are not classified within class 424 ("Drug, bio-affecting and body treating compositions") and subclass 184.1 ("Antigen, epitope, or other immunospecific

immunoeffector"), as are the method claims. Applicants respectfully submit that these claims present no such undue burden.

Applicants respectfully request that the improper subdivision by restriction in these claims be withdrawn.

Should the Examiner uphold the restriction requirement with respect to Groups I and Groups II-IV and the product claim is subsequently found allowable, Applicants request rejoinder of withdrawn process claims which include all the limitations of the allowable product claim for examination (M.P.E.P. §821.04).

CONCLUSION

Applicant requests reconsideration of the restriction requirement and examination of the elected subject matter on the merits.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882001500. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: August 15, 2001

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